



*Brain Structure and Clinical Endpoints in Myotonic
Dystrophy Type 2 (BraCE-DM2)*

BIOSPECIMEN COLLECTION & PROCESSING

Overview

1. Specimen uniformity and quality
2. Site Equipment
3. Procedures
 - Kit Ordering
 - Sample Labels
 - Sample Collection and Processing
 - Shipping Closures
4. Contact Information

Specimen Uniformity and Quality

GENERAL REMINDERS

Specimen Uniformity and Quality

Most biomarkers are sensitive to *time* and *temperature*

- Standardization of processing across sites is key
- Reference the *BioSEND Specimen Collection, Processing, and Shipment Manual* as needed
- Do not replace or supplement any kit components without first receiving approval from BioSEND/NINDS

Questions? Email biosend@iu.edu

Site Equipment

Sites will need to supply the following items:

- Gloves
- Alcohol wipes
- Butterfly needles
- Tourniquet
- Gauze pads
- Bandages
- Microcentrifuge tube rack
- Sharps bin and lid
- Crushed ice
- Pipettes and pipette tips
- Centrifuge capable of maintaining 4°C
- -80°C Freezer
- Dry ice

Collection Protocol

Collection Tube	Drawn At	Specimen Type	Aliquot Volume	Total Number of Aliquots	Cryovial Cap Color	Shipping Temperature
2 EDTA (glass) Blood Collection Tubes, 10ml	Visit 1	Plasma	1.5ml	6	Purple	Frozen
	Visit 1	Buffy Coat	~750ul	2	Clear	Frozen

Kit Ordering – Biosend.org

The screenshot shows the Biosend.org website navigation menu. At the top left is the **NINDS BioSEND** logo. To its right are five main navigation categories: **Accessing Biospecimens**, **Banking Samples**, **Active Studies**, and **About BioSEND**. The **Active Studies** category is expanded, showing a list of study resource pages: AJPD Study Resources, CHANGE-HD Study Resources, DLB Study Resources, DVRP Study Resources, EpiBioS4Rx Study Resources, LBD Study Resources, LETBI Study Resources, MBPS Study Resources, PBS Study Resources, PHD3 Study Resources, PSP Study Resources, SBPD Study Resources, CRC-SCA Study Resources, READISCA Study Resources, SPARX3 Study Resources, Udall Study Resources, Holiday Closures, Shipping Information, and Sample Shipment Form. Below the navigation menu are three image-based buttons: **About BioSEND** (with a photo of a building and trees), **Banking Samples** (with a photo of a metal container), and **Biospecimens** (with a photo of a laboratory setting).

Under “Active Studies”,
select the Study Resource
page for your protocol

Kit Ordering

Direct link to ordering system :

<http://kits.iu.edu/biosend/bracedm2>

On the Study Resources Page, follow Kit Request Module link



BioSEND Accessing Biospecimens Banking Samples Active Studies About BioSEND

Clinical Research Consortium for SCA (CRC-SCA) Study Page

Welcome CRC-SCA Study staff, coordinators, and PIs. This section encompasses study specific tools and resources for your reference. If you have any questions, comments, or new ideas please contact biosend@iu.edu or by phone directly at (317)278-0594.

Specimen Table

Cohort	Population	Plasma	Genomic DNA	Serum	CSF
MBPS	Participants with a diagnosis of SCA 1, 2, 3, 6, or 7	✓	✓	✓	✓

Study Resources

Kit Request Module

Please follow the below link to access the CRC-SCA Kit Request Module. This link will direct you to a REDCap database where study coordinators and staff may request kits, individual supplies, and/or labels. Please allow a total of two weeks for kit requests to be compiled and delivered to your site.

[Kit Request System](#)

Downloads

- Sample Shipment Form (pdf)
- Manual of Procedures
- New Coordinator Training Slides

Additional Resources

- Online Sample Form
- Kit Request System

Contact Us

biosend@iu.edu
317-278-0594

Confirm/Update Shipping Information

Select your Study Site from the drop down box to populate the most current information we have for your site. Please confirm or update your site's information as needed.

Study Site <small>* must provide value</small>	Indiana University
Indiana University School of Medicine Carolyn Dunifon Dept. of Medical & Molecular Genetics 351 West 10th Street, TK-318 Indianapolis, IN 46202-3002 (317) 274-5751 cdunifon@iu.edu	
Is the contact name above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No reset
New Contact Name <small>* must provide value</small>	Claire Wegel
Is the shipping address above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No reset
Is the e-mail address above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No reset
Is the phone number above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No reset

Note: The form includes blue arrows pointing to the 'Study Site' dropdown, the contact information text, and the 'New Contact Name' input field. Dashed boxes highlight the 'Study Site' dropdown and the 'Verify contact information and update if needed' text.

Kit Ordering – Kit Options

Selecting a kit option will populate contents

Kit Type

****Please allow two weeks for shipment****

* must provide value

Blood Collection Kit

Shipping Kit

Extra Supplies

Please specify in comments if you need kits before the standard two week shipment time.

Each Blood Collection Kit contains:

- 2 - EDTA tube, 10ml (glass)
- 6 - Cryovial (Sarstedt®) with purple cap, 2ml
- 2 - Cryovial (Sarstedt®) with clear cap, 2ml
- 2 - Disposable pipette, 3ml
- 2 - Resealable tube pouch
- 1 - Cryobox, 25 slot
- 1 - Specimen/Case label set

Kit Ordering – Blood Collection Kit

Kit Type
****Please allow two weeks for shipment****
** must provide value*

Blood Collection Kit
 Shipping Kit
 Extra Supplies

Please specify in comments if you need kits before the standard two week shipment time.

Standard collection kit for plasma and buffy coat. Contains supplies for one subject-visit.

Shipping Kits

Kit Type
****Please allow two weeks for shipment****
* must provide value

Blood Collection Kit
 Shipping Kit
 Extra Supplies

Please specify in comments if you need kits before the standard two week shipment time.

Comments

Expand

Each Shipping Kit contains:

Shipping kits contain the supplies to ship up to two subject visits' worth of samples (that is, two cryoboxes may be shipped in a single shipper).

- 2 - Plastic Biohazard bag with absorbent sheet (small)
- 1 - UPS Airbill Sleeve
- 1 - Shipping box/Styrofoam container
- 1 - UN3373 label
- 1 - Fragile label
- 1 - Dry ice label

- Shipping Kits are ordered independently of Blood Kits

- A single Shipping Kit may be used to send samples for 1-2 cryoboxes

Extra Supplies

This option allows you to order individual kit components. For ex, if you have a kit with blood tubes that have expired, you may order new collection tubes to replace them.

Kit Type **Please allow two weeks for shipment** <small>* must provide value</small>	<input type="checkbox"/> Blood Collection Kit <input type="checkbox"/> Shipping Kit <input checked="" type="checkbox"/> Extra Supplies
<small>Please specify in comments if you need kits before the standard two week shipment time.</small>	
Individual tube bubble pouch	<input type="radio"/> 2 <input type="radio"/> 4 reset
Cryobox	<input type="radio"/> 2 <input type="radio"/> 4 reset
Cryovial (Sarstedt®) with purple cap, 2ml	<input type="radio"/> 10 <input type="radio"/> 20 reset
Cryovial (Sarstedt®) with clear cap, 2ml	<input type="radio"/> 10 <input type="radio"/> 20 reset
Air waybill envelope	<input type="radio"/> 2 <input type="radio"/> 4 <small>Plastic envelope to affix air waybill to package</small> reset
Shipping Container for Dry Ice Shipments	<input type="radio"/> 2 <input type="radio"/> 4 reset
Biohazard bag with absorbent sheet	<input type="radio"/> 2 <input type="radio"/> 4 reset

Submit Request

- Click “Submit” to send order to BioSEND; staff will confirm receipt of your order
- Please allow **two week** turn-around time for kit shipments
- If urgent request needed, please note date needed by in comments and email BioSEND. We cannot guarantee urgent requests, but will do our best to accommodate.

NINDS
BIOSEND

NINDS Biosend BraCE-DM2 Kit Request System

Study Site * must provide value

Wake Forest University
[Shipping contact name]
[Address to where kits should be sent]
[Email address]
[Phone number]

Is the contact name above correct? Yes No * must provide value [reset](#)

Is the shipping address above correct? Yes No * must provide value [reset](#)

Is the e-mail address above correct? Yes No * must provide value [reset](#)

Is the phone number above correct? Yes No * must provide value [reset](#)

Kit Type Blood Collection Kit
****Please allow two weeks for shipment**** Shipping Kit
* must provide value Extra Supplies
Please specify in comments if you need kits before the standard two week shipment time.

Comments
[Expand](#)

Submit

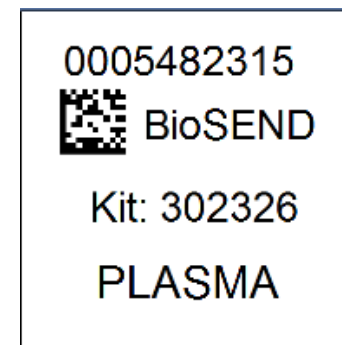
Sample Labelling

Labels are provided by Indiana University for BioSEND samples only

- Please check that all samples are properly labelled with correct specimen type



Kit Labels



Specimen Labels

Sample Labelling – Kit Labels

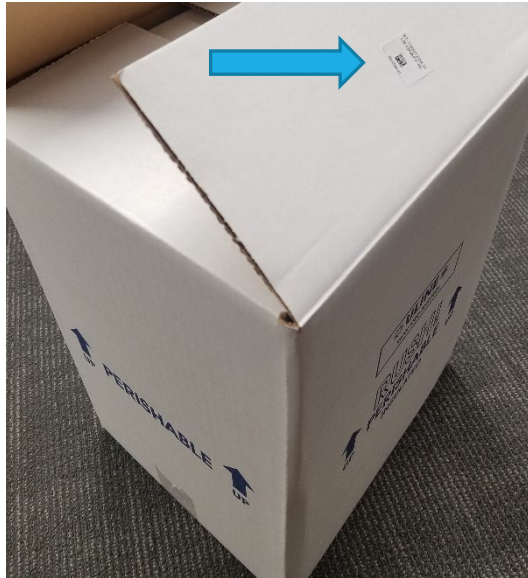


Each Blood Collection Kit will have a unique “Kit Number” used to track participant samples and provide quality assurance

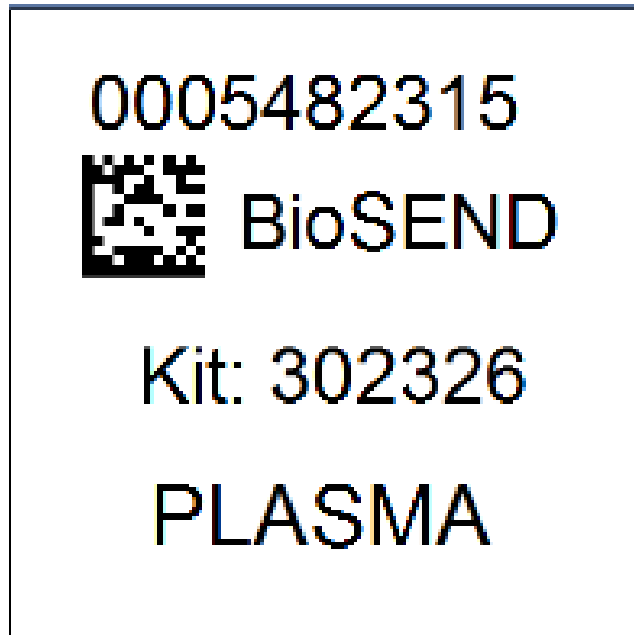
Sample Labelling – Kit Labels

Kit labels are placed:

- On the biohazard bags
- On the lid of frozen shippers



Sample Labelling – Specimen Labels



Unique Barcode



Biorepository Name



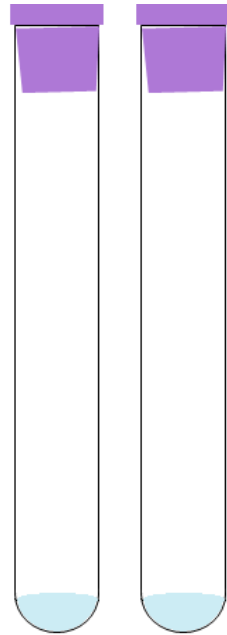
Kit Number



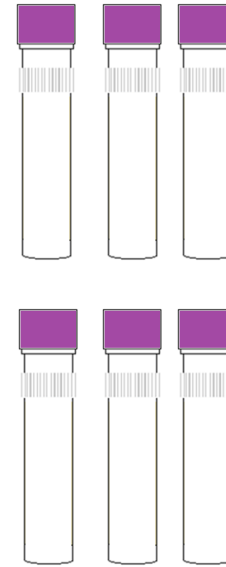
Sample Type

Sample Collection and Processing

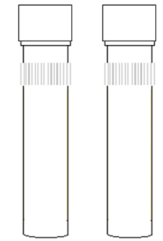
*Supplies provided for the collection of
plasma and buffy coat*



2 x 10ml EDTA (glass)
collection tubes

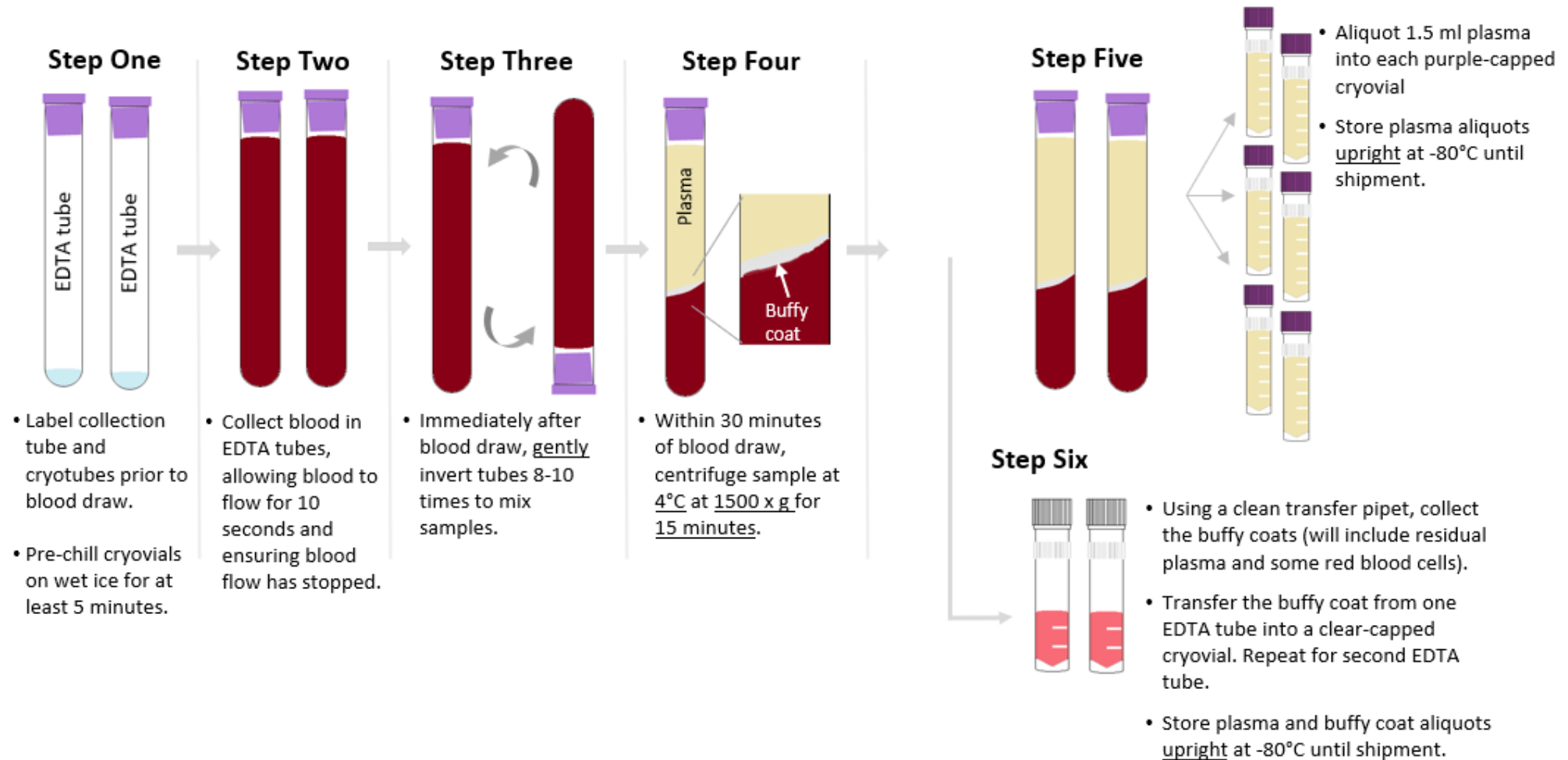


6 x 2ml Cryovials
(purple-capped) for
plasma aliquots



2 x 2ml Cryovials
(clear-capped) for
buffy coat aliquots

Sample Collection and Processing: Plasma & Buffy Coat



Shipping Samples: Frozen

Packing and Shipping Frozen Samples

- All CRC-SCA samples ship frozen
- Ship frozen samples on dry ice
- Frozen samples should be shipped **Monday through Wednesday only**



Shipping Samples: Frozen

Packing and Shipping Frozen Samples

- Fill shippers with a minimum of 10lbs of dry ice
- Place cryobox and whole blood in separate biohazard bags
- Place layer of dry ice in between biohazard bags
- Do not pack shipment until the day of pickup



Class 9 Dry Ice Label should not be covered with other stickers and must be completed correctly, or courier will reject/return your package!

Shipping Samples

Labeling frozen shippers

Shipper's Declaration not Required.

Dry Ice amount must be in kilograms.

Note: 2 lbs. = 1 kg.

Airwaybills / airbills must have the following:
1. Dry Ice; 9; UN 1845
2. $\frac{\quad}{\text{(Number pkgs)}} \times \frac{\quad}{\text{(wt)}} \text{ Kg}$

Dry Ice kg.

9

UN 1845

Shipper's Name and Address

Consignee Name and Address

06426 1/01 RRD

Net weight of dry ice in kg

Your name & address

IU information and address

Shipping Samples


UPS resources available on BioSEND website on the “Shipping Information” page

The screenshot shows the BioSEND website navigation menu. The logo is 'NINDS BioSEND'. The main navigation items are 'Accessing Biospecimens', 'Banking Samples', 'Active Studies', and 'About BioSEND'. A blue arrow points from 'Banking Samples' to 'Active Studies'. Below 'Active Studies' is a dropdown menu with the following items: 'AJPDP Study Resources', 'CHANGE-HD Study Resources', 'DLB Study Resources', 'DVRP Study Resources', 'EpiBioS4Rx Study Resources', 'LBD Study Resources', 'LETBI Study Resources', 'MBPS Study Resources', 'PBS Study Resources', 'PHD3 Study Resources', 'PSP Study Resources', 'SBPD Study Resources', 'CRC-SCA Study Resources', 'READISCA Study Resources', 'SPARX3 Study Resources', 'Udall Study Resources', 'Holiday Closures', 'Shipping Information' (highlighted with a blue arrow), 'Sample Shipment Form', and 'Withdrawn Subject Notification'. Below the menu are three small images: a building with green trees, a close-up of a metal container, and a dark interior space.

NINDS BioSEND

Accessing Biospecimens Banking Samples → Active Studies About BioSEND

- AJPDP Study Resources
- CHANGE-HD Study Resources
- DLB Study Resources
- DVRP Study Resources
- EpiBioS4Rx Study Resources
- LBD Study Resources
- LETBI Study Resources
- MBPS Study Resources
- PBS Study Resources
- PHD3 Study Resources
- PSP Study Resources
- SBPD Study Resources
- CRC-SCA Study Resources
- READISCA Study Resources
- SPARX3 Study Resources
- Udall Study Resources
- Holiday Closures
- Shipping Information**
- Sample Shipment Form
- Withdrawn Subject Notification



Shipping Information Page

Links on this page to:

1. Generate airwaybills & schedule pickups
2. View printed guide on how to use ShipExec™
3. Request user account and update site address in system
4. View video tutorial for using UPS ShipExec™

UPS Shipping Resources

1 →

To generate air waybills and schedule UPS pickups for shipments to BioSEND, please visit the UPS ShipExec™ Thin Client [website](#).

2 →

For instructions on how to use the UPS ShipExec™ Thin Client website, please refer to the [BioSEND UPS ShipExec™ Thin Client Guide](#)

3 →

To request a new user account for UPS ShipExec™ Thin Client or to request an update to your site's address in the system, please [use this form](#) to submit your request.

Navigating UPS ShipExec™

4 →

The screenshot shows a video player interface for the 'UPS ShipExec™ Thin Client Home Page'. The video content displays the following elements:

- A browser address bar with the URL: `https://kb.iu.edu/d/adad`
- A navigation bar with the 'ShipExec™' logo and menu items: 'Shipping', 'Help', and 'User of the Day'.
- A main heading: 'Welcome to the ShipExec™ Thin Client Home Page'
- Two notification sections: 'System Notifications' and 'Company Notifications'. The 'System Notifications' section includes links for 'ShipExec Documentation' and 'Importing Your Personal Address Book'.
- A large play button in the center of the video frame.
- A video player control bar at the bottom showing a progress indicator at 0:58 / 9:18, a volume icon, a CC icon, and a 1x zoom level.

Shipping Samples – UPS ShipExec™

If you will be assisting in shipping samples, please request a user account and familiarize yourself with the system well in advance of your first sample shipment

Shipping Samples: Frozen

Please notify BioSEND ahead of shipment

- Email biosend@iu.edu with copy of Sample Form and tracking number
- OR use Online Sample form on biosend.org

Sample Record and Shipment Notification

Study: BraCE-DM2

Site Name: Indiana University

Principal Investigator: Tatiana Foroud

Coordinator: Carolyn Dunifon

Telephone: 317-224-5751

Email: cdunifon@iu.edu

Please list only ONE subject per Sample Record Summary and Shipment Notification Form

Clinical Identifier: [ID associated with clinical data]

Kit Number: 123456

Sex: M

Visit Type: Visit 1

Sample Form – Appendix I

Example Completed Form, Part 1

Sample Form – Appendix I

Example Completed Form, Part 2

Instructions: Ship Frozen Shipments Monday- Wednesday. This form must be completed for shipment of all research samples. Notify Indiana University via biosend@iu.edu in advance of shipment. Please also include a physical copy in the shipment box. Please check for holiday closure and inclement weather prior to shipping.

Date Sample(s) Shipped:

January 23rd, 2022

Tracking Number:

1Z9995FAWZ78999

Completed by Submitter/Site			
Dates of Draw	Specimen Type	Number of Tubes/ Aliquots sent to BioSEND	Notation of Problems
	DNA		
	RNA		
01/09/2022	Buffy Coat	2	
01/09/2022	Plasma	4	Low volume draw – patient dehydrated
	Serum		
	CSF		
	Whole Blood		

Contact Information: Indiana University; Email: biosend@iu.edu Ph: 317-278-0594

Shipping Samples: Online Sample Form

Contact Information

Site Name/Number

Coordinator **Telephone** **Email**

Subject Information

Study **Clinical ID** **GUID**

Subject ID (ST# from labels) **Kit Number**

Sex **Visit Type**

Sample Information

Date Sample(s) Shipped **Tracking Number**

Draw Date	Specimen Type	# of Tubes Sent	Notation of Problems
<input type="text" value="Draw Date"/>	<input type="text" value="DNA"/>	<input type="text" value="# of Tubes"/>	<input type="text" value="Notation of Problems"/>
<input type="text" value="Draw Date"/>	<input type="text" value="RNA"/>	<input type="text" value="# of Tubes"/>	<input type="text" value="Notation of Problems"/>
<input type="text" value="Draw Date"/>	<input type="text" value="Plasma"/>	<input type="text" value="# of Tubes"/>	<input type="text" value="Notation of Problems"/>
<input type="text" value="Draw Date"/>	<input type="text" value="Serum"/>	<input type="text" value="# of Tubes"/>	<input type="text" value="Notation of Problems"/>
<input type="text" value="Draw Date"/>	<input type="text" value="CSF"/>	<input type="text" value="# of Tubes"/>	<input type="text" value="Notation of Problems"/>
<input type="text" value="Draw Date"/>	<input type="text" value="Whole Blood"/>	<input type="text" value="# of Tubes"/>	<input type="text" value="Notation of Problems"/>
<input type="text" value="Draw Date"/>	<input type="text" value="Buffy Coat"/>	<input type="text" value="# of Tubes"/>	<input type="text" value="Notation of Problems"/>

Shipping Samples: Closures

Date	Holiday
January 1	New Year's Day
3 rd Monday in January	Martin Luther King, Jr Day
4 th Monday in May	Memorial Day
June 19	Juneteenth (observed)
July 4	Independence Day (observed)
1 st Monday in September	Labor Day
4 th Thursday in November	Thanksgiving
4 th Friday in November	Friday after Thanksgiving
December 25	Christmas

*Please also consider weather when shipping. UPS will post service updates on their webpage. Please reach out to BioSEND if you are unsure if it is safe to ship.

Non-Conformance

Most common non-conformance issues:

- Samples shipped for weekend/holiday delivery
- Sample form incomplete/inaccurate
- Unlabeled or mislabeled tube(s)
- Sample hemolysis



Non-Conformance

- BioSEND will notify sites directly of any issues upon receipt
- ***If you are experiencing issues, please reach out to us for help! It is much easier to prevent an issue before sample collection & shipment than trying to fix it after the fact***

Contacts

Indiana University

General Questions/Shipment Notifications:

biosend@iu.edu

Biorepository Project Manager:

Claire Wegel

cwegel@iu.edu

Tel: 317.278.6158

Biorepository Clinical Research Coordinator:

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cdunifon@iu.edu

Tel: 317.274.5751